IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	C.A. No.: 06-222 (JJF) **REDACTED - PUBLIC VERSION**

PLAINTIFF WYETH'S REPLY TO THE SECOND AMENDED COUNTERCLAIMS OF DEFENDANT IMPAX LABORATORIES, INC.

Plaintiff Wyeth for its Reply to the Second Amended Answer, Affirmative Defenses, Counterclaims And Prayer For Relief Of Defendant Impax Laboratories, Inc. ("Impax's Second Amended Counterclaims")(D.I. 154), filed pursuant to a May 17, 2007 Stipulation and Order, hereby states as follows:

1. Responding to paragraph 49 of Impax's Second Amended Counterclaims, Wyeth reasserts and realleges paragraphs 1-43 of its Complaint (D.I. 1), and denies the allegations of paragraphs 44-48 of Impax's Second Amended Counterclaims.

2. Responding to paragraph 50 of Impax's Second Amended Counterclaims, Wyeth admits, on information and belief, that Impax is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544 and another place of business at 3735 Castor Avenue, Philadelphia, Pennsylvania 19124. Wyeth lacks knowledge sufficient to form a belief as to the truth of the remaining allegations of paragraph 50 and, on that basis, denies the same.

3. Responding to paragraph 51 of Impax's Second Amended Counterclaims, Wyeth denies that "Wyeth, Inc." is its name. Wyeth admits that it is a corporation incorporated under the laws of the State of Delaware, with its principal place of business in Madison, New Jersey. Wyeth denies the remaining allegations of paragraph 51.

4. Responding to paragraph 52 of Impax's Second Amended Counterclaims, Wyeth admits that this Court has subject matter jurisdiction over the counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), but denies that Impax is entitled to any of the relief it seeks.

5. Responding to paragraph 53 of Impax's Second Amended Counterclaims, Wyeth admits that it has sued Impax for patent infringement in this Judicial District and that this Court has personal jurisdiction over Wyeth for purposes of the present litigation. In addition, Wyeth admits that venue is proper in this Court for purposes of the present litigation. Wyeth denies the remaining allegations of paragraph 53.

6. Responding to paragraph 54 of Impax's Second Amended Counterclaims, Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 54 and, on that basis, denies the same.

7. Responding to paragraph 55 of Impax's Second Amended Counterclaims, Wyeth admits that it is an innovative, research-based, pharmaceutical company with a long history of pioneering developments in pharmaceuticals and biotechnology that have improved the lives of millions of people around the world. Wyeth admits that in 2005 it had over $18 billion dollars in revenue and over $3 billion dollars in net income.

Wyeth also admits that after undergoing a lengthy, costly, and uncertain research and development process to obtain FDA approval, Wyeth began selling an immediate release dosage form of venlafaxine hydrochloride under the brand name Effexor® in 1994 in the United States.

Wyeth, however, recognized the shortcomings of immediate release Effexor® early on, and began working towards possible solutions to those shortcomings with the development of an extended release product even before the immediate release Effexor® product was ever approved or sold.

After undergoing yet another lengthy, costly, and uncertain research and development process to obtain FDA approval for the extended release dosage form of venlafaxine hydrochloride that it developed, Wyeth began selling an extended release dosage form of venlafaxine hydrochloride under the brand name Effexor® XR in 1997 in the United States. Wyeth further admits that it still sells immediate release venlafaxine hydrochloride under the brand name Effexor® for the treatment of depression in the United States, but states that the sales of Effexor® are but a small fraction of the sales of Effexor® XR. Wyeth denies the remaining allegations of paragraph 55.

8. Responding to paragraph 56 of Impax's Second Amended Counterclaims, Wyeth admits that it owns U.S. Patent No. 4,535,186 ("the '186 patent"), which includes claims directed to the compound venlafaxine hydrochloride. Wyeth further admits that the United States Patent and Trademark Office ("PTO") extended the expiration date of the '186 patent from December 13, 2002 to December 13, 2007 pursuant to 35 U.S.C. § 156. In further recognition of Wyeth's additional pediatric clinical research, the FDA has extended the patent exclusivity period for the '186 patent to June 13, 2008. Wyeth denies the remaining allegations of paragraph 56.

9. Responding to paragraph 57 of Impax's Second Amended Counterclaims, Wyeth admits that provisional Application No. 60/014,006 ("the '006 application"), was filed on March 25, 1996. Wyeth also admits that utility application, Serial No. 08/821,137 ("the '137 application"), claiming priority to the '006 application, was filed on March 20, 1997. Wyeth

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admits that on November 5, 1997, prior to the abandonment of the '137 application, a continuation-in-part application, Serial No. 08/964,328 ("the '328 application"), claiming priority to the '006 and '137 applications, was filed. Wyeth also admits that on January 20, 2000, prior to the abandonment of the '328 application, a continuation-in-part application, Serial No. 09/488,629 ("the '629 application"), claiming priority to the '006, '137, and '328 applications was filed. Wyeth further admits that the '629 application issued as United States Patent No. 6,274,171 B1 ("the '171 patent"). Wyeth admits that on June 19, 2001, prior to the issuance of the '171 patent, a divisional application, Serial No. 09/884,412 ("the '412 application"), claiming priority to the '006, '137, '328, and '629 applications, was filed. Wyeth further admits that the '412 application issued as United States Patent No. 6,419,958 B2 ("the '958 patent"). Wyeth also admits that on September 12, 2001, prior to the issuance of the '958 patent, a continuation application, Serial No. 09/950,965 ("the '965 application"), claiming priority to the '006, '137, '328, '629, and '412 applications, was filed. Wyeth admits that the '965 application issued as United States Patent No. 6,403,120 B1 ("the '120 patent").

Wyeth further admits that the '171 patent, the '120 patent, and the '958 patent (collectively, "the patents-in-suit") were issued by the United States Patent and Trademark Office to inventors Deborah M. Sherman, John C. Clark, John U. Lamer, and Steven A. White. Wyeth further admits that in 2002, American Home Products Corporation changed its name to Wyeth, which owns the patents-in-suit. Wyeth denies the remaining allegations of paragraph 57.

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12. Responding to paragraph 60 of Impax's Second Amended Counterclaims,

Wyeth further states that it did notify the PTO of

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published PCT patent application WO 94/27589 and that published application was considered by the PTO during the prosecution of the patents-in-suit. Wyeth denies the remaining allegations of paragraph 60 of Impax's Second Amended Counterclaims.

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18. Responding to paragraph 66 of Impax's Second Amended Counterclaims, Wyeth admits that the administration of Wyeth's Effexor® XR product to patients in accordance with its package insert is a commercial embodiment of the asserted claims of the patents-in-suit. Wyeth denies the remaining allegations of paragraph 66.

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21. Responding to paragraph 69 of Impax's Second Amended Counterclaims, Wyeth admits that Wyeth disclosed PCT application WO 94/27589, listing a publication date of December 8, 1994 and a priority date of May 27, 1993, to the PTO. The PTO fully considered the application and determined that it did not anticipate or render obvious any claim of the patents-in-suit. Wyeth further admits that the WO 94/27589 application does not disclose any *in vivo* measurements such as peak blood plasma levels or evaluation of incidences of nausea and emesis in subjects, but denies that such properties are inherently disclosed in the PCT application WO 94/27589.

Wyeth further denies that in Wyeth's Response to Impax's Request for Admission No. 51, it admitted that the WO 94/27589 application discloses "controlled release forms" of venlafaxine hydrochloride. While Wyeth admits that the WO 94/27589 application purports to disclose "controlled release dosage forms" of a class of compounds which includes venlafaxine hydrochloride, Wyeth also states that there are insufficient details in the WO 94/27589

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application to even fully describe, much less reproduce, any formulation. Wyeth denies the remaining allegations of paragraph 69.

22. Wyeth denies the allegations of paragraph 70 of Impax's Second Amended Counterclaims.

23. Responding to paragraph 71 of Impax's Second Amended Counterclaims, Wyeth admits that Deborah Sherman is one of the inventors of the patents-in-suit.

Wyeth denies the remaining allegations of paragraph 71 of Impax's Second Amended Counterclaims.

25. Wyeth denies the allegations of paragraph 73 of Impax's Second Amended Counterclaims.

26. Wyeth admits that paragraph 74 of Impax's Second Amended Counterclaims accurately quotes a passage (with emphasis added by Impax) contained in the '006 application, as originally filed with the PTO, relating to extended release venlafaxine hydrochloride, the use

of which is claimed in each of the patents-in-suit. Wyeth denies the remaining allegations of paragraph 74.

27. Responding to paragraph 75 of Impax's Second Amended Counterclaims, Wyeth admits that on May 16, 1996, Wyeth-Ayerst Laboratories submitted NDA No. 20-699 to the FDA. At that time, Wyeth-Ayerst Laboratories was a division of American Home Products Corporation. In 2002, American Home Products Corporation changed its name to Wyeth. Wyeth admits that Wyeth-Ayerst Laboratories submitted NDA No. 20-699 for the purpose of obtaining approval to market Effexor® XR (an extended release formulation of venlafaxine hydrochloride) in the United States. Wyeth denies the remaining allegations of paragraph 75.

28. Responding to paragraph 76 of Impax's Second Amended Counterclaims, Wyeth admits that NDA No. 20-699 as submitted on May 16, 1996 indicated that clinical studies "208-US" ("Study 208"), "209-US" ("Study 209") and "367-EU" ("Study 367") on Effexor® XR had been completed. Wyeth denies the remaining allegations of paragraph 76.

29. Responding to paragraph 77 of Impax's Second Amended Counterclaims, Wyeth admits that the cover letter to the May 16, 1996 submission of NDA No. 20-699 describes "*Protocol 600-B-208-US*" as a "double-blind, flexible-dose, twelve-week efficacy study of 75-150 mg venlafaxine ER, 75-150 mg Effexor, and placebo in outpatients with major depression." Wyeth further admits that it sells an immediate release tablet formulation of venlafaxine hydrochloride under the brand name Effexor®. Wyeth denies the remaining allegations of paragraph 77.

30. Responding to paragraph 78 of Impax's Second Amended Counterclaims, Wyeth admits that the cover letter to the May 16, 1996 submission of NDA No. 20-699 describes "*Protocol 600-B-209-US*" as a "double-blind, flexible-dose, eight-week efficacy study of 75-225

mg venlafaxine ER and placebo in outpatients with major depression." Wyeth denies the remaining allegations of paragraph 78.

31. Responding to paragraph 79 of Impax's Second Amended Counterclaims, Wyeth admits that the cover letter to the May 16, 1996 submission of NDA No. 20-699 describes "*Protocol 600-B-367-UK*" as a "double-blind, fixed-dose, eight-week efficacy study of 75 and 150 mg venlafaxine ER, 20 mg Paxil, and placebo in outpatients with major depression." Wyeth denies the remaining allegations of paragraph 79.

32. Responding to paragraph 80 of Impax's Second Amended Counterclaims, Wyeth admits that Study 208, Study 209 and Study 367 comprise the "two eight-week and one 12 week clinical studies" referenced in the third sentence of the quotation from the '006 application in paragraph 74 of Impax's Second Amended Counterclaims. Wyeth denies the remaining allegations of paragraph 80.

33. Responding to paragraph 81 of Impax's Second Amended Counterclaims, Wyeth admits that patients in Study 208 received extended release venlafaxine, immediate release venlafaxine tablets, or placebo; patients in Study 209 received extended release venlafaxine or placebo; and patients in Study 367 received extended release venlafaxine, paroxetine, or placebo. Wyeth further admits that patients in Studies 209 and 367 did not receive immediate release venlafaxine hydrochloride tablets. Wyeth denies the remaining allegations of paragraph 81.

34. Wyeth denies the allegations of paragraph 82 of Impax's Second Amended Counterclaims. Responding further, Wyeth denies Impax's allegation that "the only study directly comparing the two formulations did not show the claimed statistical significance." Wyeth further states that during the prosecution of the patents-in-suit, Wyeth never represented

to the PTO that each clinical study, standing alone, established a statistically significant improvement of Effexor® XR over immediate release Effexor®.

35. Responding to paragraph 83 of Impax's Second Amended Counterclaims, Wyeth admits that patients in Studies 209 and 367 did not receive immediate release venlafaxine hydrochloride tablets. Wyeth further states that during the prosecution of the patents-in-suit, Wyeth never represented to the PTO that each clinical study, standing alone, established a statistically significant improvement of Effexor® XR over immediate release Effexor®. Wyeth denies the remaining allegations of paragraph 83.

36. Wyeth denies the allegations of paragraph 84 of Impax's Second Amended Counterclaims.

37. Responding to paragraph 85 of Impax's Second Amended Counterclaims, Wyeth states that during the prosecution of the patents-in-suit, Wyeth never represented to the PTO that each clinical study, standing alone, established a statistically significant improvement of Effexor® XR over immediate release Effexor®. Wyeth denies the remaining allegations of paragraph 85 of Impax's Second Amended Counterclaims.

38. Wyeth denies the allegations of paragraph 86 of Impax's Second Amended Counterclaims.

39. Wyeth denies the allegations of paragraph 87 of Impax's Second Amended Counterclaims.

40. Responding to paragraph 88 of Impax's Second Amended Counterclaims, Wyeth admits that the current FDA-approved package insert for Effexor® XR does not contain a statement that Effexor® XR showed "a statistically significant improvement in nausea" over Effexor®. Wyeth further admits that the current FDA-approved package insert includes some

information on immediate release Effexor®. Wyeth denies the remaining allegations of paragraph 88 of Impax's Second Amended Counterclaims.

41. Wyeth denies the allegations of paragraph 89 of Impax's Second Amended Counterclaims.

42. Wyeth denies the allegations of paragraph 90 of Impax's Second Amended Counterclaims.

43. Wyeth denies the allegations of paragraph 91 of Impax's Second Amended Counterclaims.

44. Responding to paragraph 92 of Impax's Second Amended Counterclaims, Wyeth admits that the Cunningham article states that it was authored by Lynn A. Cunningham, M.D. In addition, the words, "for the Venlafaxine XR 208 Study Group" appear after his name on the first page of the article. Wyeth further admits that the Cunningham article describes certain results from Study 208. Wyeth further admits that the Cunningham article states that "[t]his study was supported by Wyeth-Ayerst Research, Radnor, Pennsylvania." Wyeth further admits that at the time of the Cunningham article Wyeth-Ayerst Research was affiliated with American Home Products Corporation. Wyeth denies the remaining allegations of paragraph 92 of Impax's Second Amended Counterclaims.

45. Wyeth denies the allegations of paragraph 93 of Impax's Second Amended Counterclaims.

46. Responding to paragraph 94 of Impax's Second Amended Counterclaims, Wyeth admits that the Cunningham article discusses certain results from Study 208. In addition, Wyeth admits that paragraph 78 of Impax's Second Amended Counterclaims accurately quotes a sentence in the Cunningham article with the exception of a missing hyphen and the added

bracketed material. Wyeth denies the remaining allegations of paragraph 94 of Impax's Second Amended Counterclaims.

47. Wyeth denies the allegations of paragraph 95 of Impax's Second Amended Counterclaims.

48. Wyeth denies the allegations of paragraph 96 of Impax's Second Amended Counterclaims.

49. Responding to paragraph 97 of Impax's Second Amended Counterclaims, Wyeth admits that the patents-in-suit were issued by the United States Patent and Trademark Office. Wyeth further admits that each of the patents-in-suit claim priority to the same provisional patent application No. 60/014,006, filed on March 25, 1996. Wyeth denies the remaining allegations of paragraph 97.

50. Responding to paragraph 98 of Impax's Second Amended Counterclaims, Wyeth admits that Wyeth obtained FDA approval for the extended release venlafaxine hydrochloride product Effexor® XR. While U.S. sales of Effexor® plateaued at about $225 million per year, U.S. sales of Effexor® XR have steadily increased to over $2 billion per year. The benefits of Effexor® XR as compared to Effexor® are reflected in the significant differences in market performance for those products and explain the commercial success of Effexor® XR. Wyeth denies the remaining allegations of paragraph 98.

51. Responding to paragraph 99 of Impax's Second Amended Counterclaims, Wyeth admits that Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA with the FDA to obtain approval to manufacture, use and sell an extended release venlafaxine hydrochloride dosage form. Wyeth denies that Teva's certification letter to Wyeth stated that the '171, '120 and '958 patents' method claims would not be infringed by Teva. In fact, Teva's certification letter to

Wyeth did not dispute Teva's infringement of the method claims of the patents-in-suit. Wyeth further admits that Wyeth sued Teva for patent infringement in the United States District Court, District of New Jersey. Wyeth also admits that a Markman hearing was held in that litigation after extensive discovery and that the Court issued a Markman Order which was later vacated. A copy of the Court's Order vacating its own Markman Order is attached as Exhibit A. Wyeth admits that the litigation with Teva was settled and that certain terms of the settlement remain confidential. However, Wyeth states that the settlement agreement was provided to the judge in the New Jersey litigation with Teva as well as to the FTC. Wyeth denies the remaining allegations of paragraph 99.

52. Responding to paragraph 100 of Impax's Second Amended Counterclaims, based on pages 003138-40 (IMPAX0003706-08) of what Impax purports to be ANDA No. 78-057, microcrystalline cellulose is not listed as an ingredient of Impax's venlafaxine extended release formulation. Wyeth denies the remaining allegations of paragraph 100.

53. Responding to paragraph 101 of Impax's Second Amended Counterclaims, Wyeth reasserts and realleges paragraphs 1-52, above.

54. Responding to paragraph 102 of Impax's Second Amended Counterclaims, Wyeth admits that an actual controversy exists between Wyeth and Impax with respect to enforceability, infringement, and validity of the patents-in-suit. Wyeth states that the patents-in-suit are enforceable, valid, and infringed by Impax. Wyeth denies that Impax is entitled to any of the relief it seeks and denies the remaining allegations of paragraph 102.

55. Wyeth admits the allegations of paragraph 103 of Impax's Second Amended Counterclaims.

56. Wyeth denies the allegations of paragraph 104 of Impax's Second Amended Counterclaims.

57. Wyeth denies the allegations of paragraph 105 of Impax's Second Amended Counterclaims.

58. Wyeth denies the allegations of paragraph 106 of Impax's Second Amended Counterclaims.

59. Wyeth denies the allegations of paragraph 107 of Impax's Second Amended Counterclaims.

60. Wyeth denies the allegations of paragraph 108 of Impax's Second Amended Counterclaims.

61. Wyeth denies the allegations of paragraph 109 of Impax's Second Amended Counterclaims.

62. Wyeth denies the allegations of paragraph 110 of Impax's Second Amended Counterclaims.

63. Wyeth denies the allegations of paragraph 111 of Impax's Second Amended Counterclaims.

64. Responding to paragraph 112 of Impax's Second Amended Counterclaims, Wyeth reasserts and realleges paragraphs 1-52, above.

65. Responding to paragraph 113 of Impax's Second Amended Counterclaims, Wyeth admits that an actual controversy exists between Wyeth and Impax with respect to enforceability, infringement, and validity of the patents-in-suit. Wyeth states that the patents-in-suit are enforceable, valid, and infringed by Impax. Wyeth denies that Impax is entitled to any of the relief it seeks and denies the remaining allegations of paragraph 113.

66. Responding to paragraph 114 of Impax's Second Amended Counterclaims, Wyeth admits that during the prosecution of the patents-in-suit, the inventors of the patents-in-suit and attorneys responsible for prosecuting the patents-in-suit had a duty of candor and good faith in dealing with the PTO, including a duty to disclose to the PTO all information known to that individual to be material to patentability. Wyeth denies the remaining allegations of paragraph 114 of Impax's Second Amended Counterclaims.

67. Wyeth denies the allegations of paragraph 115 of Impax's Second Amended Counterclaims.

68. Wyeth denies the allegations of paragraph 116 of Impax's Second Amended Counterclaims.

69. Wyeth denies the allegations of paragraph 117 of Impax's Second Amended Counterclaims.

70. Wyeth denies the allegations of paragraph 118 of Impax's Second Amended Counterclaims.

71. Wyeth denies the allegations of paragraph 119 of Impax's Second Amended Counterclaims.

72. Wyeth denies the allegations of paragraph 120 of Impax's Second Amended Counterclaims.

73. Wyeth denies the allegations of paragraph 121 of Impax's Second Amended Counterclaims.

74. Wyeth denies the allegations of paragraph 122 of Impax's Second Amended Counterclaims.

75. Wyeth denies the allegations of paragraph 123 of Impax's Second Amended Counterclaims.

76. Wyeth denies that Impax is entitled to any of the relief it seeks.

PRAYER FOR RELIEF

WHEREFORE, Wyeth respectfully requests that this Court enter judgment against Impax and that the Court enter an Order:

(1) dismissing Impax's Second Amended Counterclaims with prejudice;

(2) granting Wyeth the relief it requests in its Complaint;

(3) awarding Wyeth its attorneys' fees and costs; and

(4) awarding Wyeth such further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL, LLP

/s/ Karen Jacobs Louden

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June 14, 2007
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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No.: 03-1293 (WJM)

ORDER VACATING MARKMAN RULINGS

Having considered the parties Joint Motion to Vacate Markman Rulings, and as a result of the parties' having executed the Settlement and Release Agreement dated November 2, 2005, the Court hereby Orders that:

The September 6, 2005 Markman Opinion and Order, and the October 6, 2005, Letter Opinion and Order denying Wyeth's Request for Reconsideration of the Markman Opinion and Order, are hereby vacated.

SO ORDERED THIS 12th day of January, 2006

William J. Martini, U.S.D.J.

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on June 20, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer
MORRIS JAMES LLP

I also certify that copies were caused to be served on June 20, 2007upon the following in the manner indicated:

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